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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/781,263

02/19/2004

Yoshiyuki Inada

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EXAMINER

LOEWE, SUN JAE Y

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

01/12/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/781,263 | Applicant(s) INADA ET AL. | |
| | Examiner SUN JAE Y. LOEWE | Art Unit 1626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9-10-2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-10 are pending in the instant application.

Response to Amendment

2. The amendments and remarks filed on September 10, 2008 have been considered. The following grounds of objection/rejection have been obviated and are thus hereby withdrawn: a) objection to the specification; b) obviousness double patenting rejection over US 6,420,405 (see below Section 5).

Note: Section numbers refer to those from the office action dated March 25, 2008.

3. The following grounds of rejection are maintained and hereby made FINAL: a) objection to the oath/declaration (Section 3); b) objection to supplemental oath/declaration (Section 4); c) rejection of claims as being based on defective oath (Section 5); d) 35 USC 112 1st paragraph rejection (Section 7); e) 35 USC 103 rejection (Section 8); obviousness double patenting rejections (Section 9-11, 13, 14).

Note: Section numbers refer to those from the office action dated March 25, 2008.

4. Maintained Objection to the Oath/Declaration
Applicant is requested to properly claim foreign priority. Applicant is also requested to properly identify 37 CFR 1.56(a).

Maintained 35 USC 112 1st Paragraph Rejection

„ The safety of a pharmaceutical product is not a condition of patentability

.....

„ Strauss et al. ignores results of CHARM study that demonstrates reduction of myocardial infarction by candesartan

.....

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In sum, the PTO's rejection relies on a controversial theory, which ignores real experimental results demonstrating the reduction of the risk of MI by the claimed angiotensin II antagonists. For this reason alone, Applicants request withdrawal of the rejection. ”

Applicant's remarks have been considered, however, they are not found to be persuasive. The cited art shows the level of unpredictability in Applicant's field of endeavor, ie. treatment of myocardial infarction using angiotensin II antagonists. It is maintained that the rejection was proper based on insufficient guidance in the instant specification, and high level of unpredictability in the art.

Maintained 35 USC 103 and Obviousness-Type Double Patenting Rejections

“ In response, Applicants note that while Naka '423 and '136 may teach the claimed angiotensin II antagonists, these documents do not teach the combination and uses of those compounds with a diuretic and/or a calcium channel blocker.

.....

Applicants submit that the PTO failed to establish any prima facie case of obviousness because the PTO failed to make an explicit analysis supporting the combination used in the rejection. ”

Applicant's remarks are noted, however, they are not found to be persuasive. Notwithstanding lack of explicit suggestion to combine the instantly claimed compound with diuretic and/or calcium channel blocker, the combination is still found to obvious for the reasons provided in the previous office action. Notably, the instant compound is an angiotensin II antagonist which art recognized to be useful in combination with the other ingredients for the instant utility. The combination is within the technical grasp of one of ordinary skill, at the time the application was filed. See also MPEP 2143, excerpts below:

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E. "Obvious To Try" – Choosing From a Finite Number of Identified, Predictable Solutions, With a Reasonable Expectation of Success

To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Then, Office personnel must articulate the following:

(1) a finding that at the time of the invention, there had been a recognized problem or need in the art, which may include a design need or market pressure to solve a problem;

(2) a finding that there had been a finite number of identified, predictable potential solutions to the recognized need or problem;

(3) a finding that one of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success; and

(4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The rationale to support a conclusion that the claim would have been obvious is that "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely that product [was] not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103." *KSR*, 550 U.S. at ___, 82 USPQ2d at 1397. If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.

Terminal Disclaimer

5. The terminal disclaimer filed on September 10, 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 6,420,405 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Information Disclosure Statement

6. The information disclosure statement (IDS) submitted on September 10, 2008 was in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. The IDS was considered. A signed copy of form 1449 is enclosed herewith.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUN JAE Y. LOEWE whose telephone number is (571)272-9074. The examiner can normally be reached on M-F 7:30-5:00 Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sun Jae Y. Loewe/
1-7-2009

/Golam M. M. Shameem/
Primary Examiner, Art Unit 1626